Remarks

Claims 1, 2, 8, and 9 are rejected as being anticipated by U.S. Patent No. 6,007,833 to Chudzik et al. (the '833 patent). Claims 3, 4, 10, 11, 13-17, 21-23, and 25 are rejected as obvious over the '833 patent in view of U.S. Patent No. 6,179,862 to Sawhney et al. (the '862 patent). Both rejections are traversed.

The Claimed Invention

Independent claim 1 recites a hydrogel wound dressing. The dressing is formed by spraying a liquid composition onto the wound. The liquid composition includes macromers that crosslink to form the hydrogel when they are sprayed upon the wound. The macromers have a PVA backbone and one or more pendant crosslinkable acrylamide groups containing olefinically unsaturated groups. Crosslinking is initiated using a crosslinking initiator- which is not bound to the macromer.

Independent claim 14 recites a method of making a hydrogel wound dressing directly on the wound by spraying a liquid composition onto the wound which crosslinks into the hydrogel as it is sprayed upon the wound. The liquid composition comprises water soluble PVA macromers having one or more pendant crosslinkable acrylamide groups containing olefinically unsaturated groups.

Dependent claims 3, 4, 16, and 17 specify that the composition is delivered using an aerosol or pump spray delivery device. Dependent claims 8, 9, 10, 21, 22, and 23 specify that the composition includes an active agent. Dependent claim 11 specifies that the dressing debrides the wound when it is removed. Dependent claims 13 and 25 specify that the crosslinking is initiator by a redox initiator.

The Cited References

The '833 patent teaches a crosslinkable macromer having two or more pendant polymerizable groups **and** one or more pendant initiator groups. The point of the invention is to avoid the use of free initiators that can present issues of toxicity, efficacy, and solubility (see col. 2, lines 15-20). To this effect, the initiators are bound to the backbone.

The Examiner states that the '833 patent teaches spray delivery because it does not teach any method of delivery at all ("US '833 teaches the liquid delivery of the composition without excluding or specifying any method of delivery, thus the spraying the [sic] liquid composition into the wound is inclusive in the reference teaching."). In fact, the '833 patent does tech a

method of delivery- it teaches applying the liquid composition via a catheter (see col. 10, lines 27-29); via syringe (see col. 16, lines 52-59); and via dip coating (see Examples 16 and 17).

The '833 patent also does not teach free radical polymerization with redox initiated crosslinking. It only discloses free radical polymerization initiated by photoinitiators (see col. 5, lines 47-51 and col. 6, lines 7-13). These photoinitiators, as mentioned above, are bound to the macromer backbone. The '833 patent does not teach redox initiators, or how such initiators could be bound to a polymer backbone. The '833 patent also teaches using hydrogen abstraction reactions, photosensitization reactions, and thermally reactive polymerization initiators.

The '862 patent teaches a method for forming a tissue adherent barrier in situ using a sprayer to deliver crosslinkable fluids. One of the fluids specifically described as suitable in the method is a solution of macromer, such as the macromer taught in US '016 (see col. 6, l. 17). In fact, the macromer of '016 is the preferred macromer for use in the system (see col. 6, ll. 18-32). As the Examiner acknowledges, US '862 does not teach a PVA based macromer.

The §102(e) Rejection

The '833 patent is cited as anticipating claims 1, 2, 8, and 9. Claim 1 recites a hydrogel wound dressing formed by spray delivery of a composition to the wound. Claim 1 does not recite an intended use for a composition, as stated by the Examiner, but rather it claims a wound dressing formed via spray. The '833 patent does not teach spray delivery of the composition taught therein. It does teach application by other means (direct liquid application via catheter or syringe and dipping), but it does not disclose spray.

A wound dressing formed by spray application of a composition offers several advantages over application via syringe, catheter, or dipping. See page 3, lines 1-12. Spray delivery can increase the penetration of the polymer into the wound area thereby potentially making the delivery of active ingredients more efficient. Penetration of the polymer into the wound bed may also aid in debridement of the wound during dressing changes to accelerate the wound healing process. With spray delivery of an in situ polymerizing polymer, a thin coating can be achieved with excellent coverage of the treated area.

As amended, claim 1 specifies that the composition includes initiator groups that are not bound to the macromer. The '833 patent requires that the initiator groups are bound.

At least these two aspects of the claimed wound dressing are not taught by the '833 patent. Accordingly, claim 1, and claims 2, 8, and 9, dependent thereon, are not anticipated by the '833 patent.

The §103(a) Rejection

The '862 and '833 patents are cited in combination as rendering claims 3, 4, 10, 11, 13-17, 21-13, and 25 obvious. Applicants agree with the Examiner that the '833 patent does not teach delivery by spray, NO as an active agent, redox initiation, or that the dressing debrides the wound when removed (see the Office Action, paragraph spanning pages 4 and 5).

As discussed above, the '833 patent does not teach forming a wound dressing by spray delivery of a composition. The '833 does specify methods of delivery of the composition, contrary to the statement otherwise by the Examiner, and those methods are not inclusive of spray delivery.

The Examiner has previously used the '862 patent to reject the claims. In the Office Action of December 18, 2002, the Examiner cited the '862 patent as anticipating and/ or rendering obvious all of the claims as pending at that time. Upon amendment of the claims to further define the macromers, the claims were rejected again (in the Office Action mailed on December 17, 2003) as obvious over the '862 patent in view of U.S. Patent No. 5,410,016. These previous rejections have now been dropped and the Examiner now attempts to use the '833 patent to supply the deficiencies of the '862 patent. But the new combination still does not fulfill the requirements of §103.

As was discussed in previous correspondence between the Applicants and Examiner, the '862 patent does not teach or suggest the macromers that are used in the present invention. It does teach spray delivery of macromers- but not those herein claimed. As discussed above, the '833 patent does not teach spray delivery, redox initiation, wound debridement, or NO as an active agent.

There exists no reason to combine the teachings of the references. Moreover, even if they are combined, the claimed invention does not result. Neither reference teaches the use of a

PVA macromer having one or more pendant crosslinkable groups and a crosslinking initiator that is not bound to a macromer.

The law requires that there be- in the references themselves- some motivation to combine the references. Nowhere does the '833 patent suggest that it would be beneficial to spray the composition taught therein and form a wound dressing. Nowhere does the '862 patent teach that it would be beneficial to use a PVA macromer having one or more pendant acrylamide groups containing olefinically unsaturated groups.

Conclusion

Reconsideration of the claims as amended is respectfully requested.

Respectfully submitted,

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Date: July 22, 2004